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On *April 19, 2004*

TOWNSEND and TOWNSEND and CREW LLP

By: *Dign Hoover*

PATENT  
Attorney Docket No.: 018563-003500US  
Client Ref. No.: AT-00073

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of:

ANH et al.

Application No.: 09/560,424

Filed: April 27, 2000

For: SYSTEMS AND METHODS FOR  
GENERATING AN APPLIANCE WITH TIE  
POINTS

Examiner: SEALEY, Lance W.

Art Unit: 2671

**APPELLANT'S BRIEF**  
**UNDER 37 C.F.R. § 1.192**

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Sir:

Appellant offers this Appeal Brief in furtherance of the Notice of Appeal filed on October 9, 2003 in the above-referenced patent application. This Appeal Brief is submitted in triplicate as required by 37 C.F.R. § 1.192(a). Please deduct the requisite fee, pursuant to 37 C.F.R. § 1.17(c), of \$330 from deposit account 20-1430, and deduct any additional fees or credit any excess fees associated with the Appeal Brief to such deposit account. Appendix A, attached hereto, contains a copy of all claims pending in this case.

REAL PARTY IN INTEREST:

All right, title, and interest in the subject invention and application are assigned to Align Technology, Inc., having offices at 881 Martin Avenue, Santa Clara, California 95050. Therefore, Align Technology, Inc. is the real party interest.

RELATED APPEALS AND INTERFERENCES:

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS:

Claims 1-20 were originally presented in the application. Claims 1-20 have been rejected. Claims 1-20 are the subject of this appeal. No other claims are pending.

STATUS OF AMENDMENTS:

A Final Office Action was mailed on February 26, 2002. An amendment under 37 C.F.R. § 1.116 was filed in response to this Final Office Action on May 29, 2003 along with a Terminal Disclaimer and Petition to Revive Unintentionally Abandoned Application. An Advisory Action was mailed on September 12, 2003 along with a Petition Dismissal as the after final amendment did not place the application in condition for allowance. A Notice of Appeal was filed on October 9, 2003 along with a Renewed Petition Under 37 C.F.R. § 1.137(b). The Petition was granted on October 23, 2003.

A copy of all the pending claims, prior to the after final amendment, is provided in Appendix A attached hereto.

SUMMARY OF THE INVENTION:

The appealed claims are directed at methods for integrating and visualizing anatomical information from a plurality of sources. Claims 1; 14; and 15. The method includes temporary placement of one or more physical marker points 12, such as radiopaque metal spheres or tie points, on the surfaces of the teeth of a patient 10 or on an appliance 50 mounted on the patient's teeth. *Id.*; Application, page 5, lines 14-15; Fig. 1. With these markers 12 in position, two or more skull X-ray images are

generated from different perspectives using an X-ray camera 20. Claims 14 and 15; Application, page 5, lines 16-17; Fig. 1. A three dimensional (3D) image-capture system 30 captures digital 3D images of both 1) the tooth surfaces and their associated markers and 2) the facial surface and its associated markers. Claims 1, 14, and 15; Application, page 6, lines 8-11; Fig. 1. Particularly, three or more measurable markers are available in common for each pair of 3D images to be integrated. *Id.* An integration system 70 receives data from the X-ray camera 20, the 3D camera 30, and a digital teeth model and aligns the data in 3D space to provide a holistic view of the patient for treatment. Claims 1, 14, and 15; Application, page 6, lines 15-18; Fig. 1. Such integration of digitally encoded graphic representations of the teeth and the facial surface make possible 3D diagnosis, treatment planning, and evaluation of results in orthodontics. Application, page 5, lines 10-13.

ISSUES:

- I. Whether claims 1-9, 11-13, 15-19, and 20 are unpatentable over claims 21-29, 31-33, 35-39, and 40 of co-pending U.S. Patent Application Serial No. 09/560,052 under the judicially created doctrine of obviousness-type double patenting.
- II. Whether claims 1, 3, 5-6, 9, and 11-13 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,152,731 issued to Jordan et al.
- III. Whether claims 2, 10, 14-16, and 19-20 are unpatentable under 35 U.S.C. § 103(a) over Jordan et al. in view of U.S. Patent No. 5,882,192 issued to Bergersen.

GROUPING OF THE CLAIMS:

Appellant submits that the claims do not stand or fall together. As Appellant will argue more fully below, claims 1, 11, and 14 each separately and independently define novel and non-obvious elements patentable over the cited art. Hence, only independent claim 1 and dependent claims 2-9, 12, and 13 stand together; dependent claims 11 and 19 stand together; and independent claims 14 and 15 and dependent claims 10, 16-18, and 20 stand together.

ARGUMENT

I. Non-statutory Double Patenting

In the Final Office Action dated February 26, 2002, claims 1-9, 11-13, 15-19, and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-29, 31-33, 35-39, and 40 of co-pending U.S. Patent Application Serial No. 09/560,052. A copy of a terminal disclaimer filed on May 29, 2003 is attached hereto as Appendix B to obviate this non-statutory double patenting rejection. Withdrawal of this rejection is respectfully requested.

II. Whether claims 1, 3, 5-6, 9, and 11-13 are anticipated by Jordan et al.

In the Final Office Action, claims 1, 3, 5-6, 9, and 11-13 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Jordan et al. Appellant respectfully traverses this rejection for the following reasons discussed below.

Generally, the present rejection does not establish *prima facie* anticipation. A single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). In the instant case, the Jordan et al. patent fails to describe or suggest several specific limitations recited in the claims of the present invention.

Independent claim 1 reads as follows:

*A method for integrating anatomical information from a plurality of sources of information, comprising:*  
*receiving two or more three dimensional (3D) anatomical maps sharing a common plane specified by three or more marker points common to the two or more maps;*  
*placing one or more marker points on one or more teeth;*  
*generating a digital model of the teeth with the marker points; and*  
*aligning the two or more 3D anatomical maps and the digital teeth model using the marker points.*

The Jordan et al. patent describes a computer implemented method of creating a dental model for use in dental articulation. Jordan et al. includes providing a first set of digital data corresponding to an upper arch image of at least a portion of an upper dental arch of a patient, providing a second set of digital data corresponding to a lower arch image of at least a portion of a lower dental arch of the patient, and providing hinge axis data representative of the spatial orientation of at least one of the upper and lower dental arches relative to a condylar axis of the patient. A reference hinge axis is created relative to the upper and lower arch images based on the hinge axis data. However, the Jordan et al. patent fails to describe or suggest several specific limitations recited in claim 1.

For example, claim 1 requires "receiving two or more three dimensional (3D) anatomical maps sharing a common plane specified by three or more marker points common to the two or more maps." No where in Jordan et al. does it show receiving two or more three dimensional (3D) anatomical maps sharing a common plane specified by three or more marker points common to the two or more maps. The Examiner argues that this specific limitation is met by block 14, Fig. 1 in the Jordan et al. patent, which is reproduced below from Col. 9, lines 18-61:

First, as generally shown by block 14, the data collection process includes capturing the three dimensional morphology of the individual dental arches of the patient. Preferably, such data includes data representative of the structure of all the teeth and the relevant gingiva, but the present invention is also of benefit when one or more portions of such dental arches are captured, e.g., one or more teeth in a section of one of the dental arches. There are a variety of methods available for providing such information and the present invention is not limited to any particular method but only as described in the accompanying claims. For example, tools which can be utilized to provide measured digital data representative of the upper and lower dental arches may include dental impressions, laser scans, stylus scans, and/or stereophotographs. The measured digital data concerning the upper and lower dental arches may be captured directly from the patient in a digital form, e.g., stereographs, or the information may be captured indirectly from the patient by removing the information from the patient in a nondigital form (e.g., dental impressions and study models) and later digitizing the information (e.g., slicing the dental impressions and digitizing the boundaries). Some of the

varied processes for providing digitized data of dental arches include, but are clearly not limited to, laser scanning, photogrammetry, and those processes described in U.S. Pat. No. 5,078,599, U.S. Pat. No. 5,131,844, U.S. Pat. No. 5,338,198, U.S. Pat. No. 4,611,288, U.S. Pat. No. 5,372,502, Article entitled "Three-dimensional dental cast analyzing system with laser scanning," by T. Kuroda, et. al., Am.J.Ortho.Dent.Othorp., Vol.110[4], October 1996, pp. 365-69, and Israeli Patent Application Serial No. 114691 previously cited herein. Preferably, the digital data representative of the dental arches of a patient is provided by the process described in Israeli Patent Application Serial No. 114691 resulting in measured digital data representative of boundaries of sliced portions of dental impressions. Further, such digital data may include calculated data representative of surfaces of the dental arches as opposed to the measured digital data. Such calculated digital data for display of surfaces can be generated in numerous ways from the measured digital data as would be known to one skilled in the art resulting in data representative of various elements used for display of such surfaces, e.g., various calculated points, meshes, polygons, etc.

In particular, Col. 9, lines 18-20 in Jordan et al. is cited to show the 3D morphology of the patient's individual arches. Final Office Action, page 3. The Examiner interprets this as "teaching two anatomical maps, one for each dental arch." Advisory Action, page 2. Appellants respectfully disagree. From the plain language of the patent, it is clear that Jordan et al. at best shows receiving a single 3D morphology. There is no indication in this reference of receiving two or more three dimensional (3D) anatomical maps. In the claimed embodiment of claim 1, the two or more 3D maps are needed for three dimensionally aligning the anatomical maps and the teeth model.

Moreover, the Jordan et al. patent is completely silent on the further limitation of "sharing a common plane specified by three or more marker points common to the two or more maps." In the claimed embodiment of claim 1, the three marker points common to the two 3D maps are needed for aligning the anatomical maps and the teeth model in 3D space. Jordan et al. does not solve this problem and hence is completely silent on this aspect. Block 14 entitled "provide data representative of upper and lower dental arches" in Fig. 1 in the Jordan et al. patent is completely silent on the use of markers.

Claim 1 further requires "placing one or more marker points on one or more teeth." No where in Jordan et al. does it show the use of a marker. The Examiner argues that this limitation is met by block 16 (Fig. 1) in the Jordan et al. patent. Final Office Action, page 4. The corresponding section is reproduced below from col. 9, line 62 through col. 10, line 9:

Second, as generally shown by block 16, the data collection process includes measuring the spatial relationship between the upper and lower dental arches of the patient to provide the bite alignment data necessary to create the dental articulation model 11. There are a variety of methods available for providing such information and the present invention is not limited to any particular method but only as described in the accompanying claims. For example, one method may include identifying at least three nonlinear points on each dental arch and measuring matched pairs of such points, i.e., a pair being one point from each arch. Such measurements may be obtained directly from the patient, i.e., in vivo, or from representations of the dental arches of the patient, such as impressions of the dental arches or dental study models.

This cited section merely indicates that there are a variety of methods available for measuring the spatial relationship between the upper and lower dental arches of the patient to provide bite alignment data. There is no correspondence between the bite alignment data of Jordan et al. and the instant invention's placement of physical markers on the teeth.

The Examiner appears to equate the "three nonlinear points in each of the upper and lower arches" to the claimed "teeth markers." Advisory Action, page 2; Col. 17, lines 52-65. Appellant respectfully disagrees. The Jordan et al. reference at best describes virtual points in vivo for bite alignment purposes. The presently claimed invention, in contrast, claims actual physical markers such as radiopaque metal spheres or tie points that are placed on teeth for aligning the anatomical maps and the teeth model in 3D space. In sum, Jordan et al. fails to show the use of markers, much less the specifics of placing one or more marker points on one or more teeth and generating a digital model of the teeth with the marker points.

Lastly, claim 1 requires "aligning the two or more 3D anatomical maps and the digital teeth model using the marker points." The Examiner appears to equate

block 11 in Fig. 1 of Jordan et al. with the claimed aligning step. Final Office Action, page 4. However, block 11 in Fig. 1 merely shows a "dental articulation model". There again is no reference to aligning the 3D anatomical maps and the teeth model using the marker points. Block 11 in Fig. 1 is completely silent on the use of markers. Further, the alignment process of Jordan et al. and those claimed in claim 1 are quite distinct. As noted in Col. 17, lines 52-65 and Fig. 7 of Jordan et al.:

With the digital data representative of the upper and lower dental arches [14] provided to the model creation program 10 along with the spatial coordinates of at least three nonlinear points in each of the upper and lower dental arches of the patient [16], the alignment routines 22 are performed as follows. The digital data representative of the upper and lower dental arches is manipulated such that corresponding points of the upper and lower arch images represented by the digital data are in the same spatial relationship as the spatial coordinates of the bite alignment data. In other words, the identifiable points of the upper and lower dental arches of the patient as provided by the bite alignment data and the corresponding identifiable points of the dental arch images are aligned.

In Jordan et al. the alignment process 22 involves aligning the upper and lower arches relative to one another by combining the data of the upper and lower arches of block 14 with the bite alignment data of block 16. In contrast, the present invention of claim 1 requires aligning the two or more 3D anatomical maps and the digital teeth model in 3D space using the marker points.

Since *prima facie* anticipation requires that each and every element of the claim is shown in the prior art, Appellant respectfully submits that Jordan et al. does not anticipate the present invention. A number of elements in the structural relationship of claim 1 are absent from this reference as discussed above in great detail. As such, it is respectfully requested that the § 102(e) rejection of independent claim 1 be withdrawn and the claim be allowed. Claims 2-13 depend from independent claim 1. As argued above, these claims should be allowable for many of the reasons given above with respect to claim 1.

Dependent claim 11 further requires that the markers comprise tie points. This additional novel and non-obvious limitation is not remotely shown or suggested in



the Jordan et al. reference. The Examiner references page 2, lines 25-27 of the specification. Final Office Action, page 4. Appellants are confused by this citation. The present application's specification (which is not prior art) has no such line numbers. As discussed above, Jordan et al. fails to teach physical markers, much less the use of tie points. This additional limitation supports the separate and independent patentability of this dependent claim.

III. Whether claims 2, 10, 14-16, and 19-20 are unpatentable over Jordan et al. in view of Bergersen

In the Final Office Action, claims 2, 10, 14-16, and 19-20 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Jordan et al. in view of Bergersen. Appellant respectfully traverses this rejection for the following reasons discussed below.

The present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and M.P.E.P. §§ 2142-2143. The Examiner bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976). To establish *prima facie* obviousness, three basic criteria must be met. M.P.E.P. § 2142. First, the Examiner must establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. §2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). Second, the Examiner must show some suggestion or motivation, either in the prior art references or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Third, the Examiner must establish that there is a reasonable expectation of success for the modifications. M.P.E.P. § 2142. Appellant respectfully submits that a *prima facie* case of obviousness has not been met because the Examiner's rejection fails on at least two of the above requirements.

First, Appellant notes that the cited art, alone or in combination (which combination is disputed), fails to teach or suggest all the claim limitations. Independent claim 14 requires in part "wearing a dental appliance with one or more teeth markers." This element has not been suggested by either the Jordan et al. or Bergersen patents. The

Examiner asserts that Bergersen discloses wearing a dental appliance with one or more teeth markers. Final Office Action, page 6. The cited section at col. 4, lines 39-43, is reproduced below:

In another embodiment, the users head is held stationary on chin support member 44 while one or more cameras 42 move relative to apparatus 20 according to the preprogrammed position for acquiring the necessary images of the user's mouth.

This cited section falls far short of a dental appliance with one or more physical teeth markers as claimed in claim 14.

Bergersen instead relates to a method and apparatus for diagnosing orthodontic conditions of an individual. The apparatus includes an outer case and a user interface disposed on the outer case for communicating with the individual. The apparatus further has diagnostic hardware including at least one digital camera carried within the case adapted to take a plurality of video images of the teeth and mouth of the individual. The apparatus further has electronic circuitry which is preprogrammed with statistical data for comparison to actual data collected by the diagnostic hardware and transmitted to the electronic circuitry. The circuitry is further adapted to diagnose whether the individual has correctable orthodontic conditions. The apparatus is further adapted to dispense instructions to the individual for receiving proper corrective orthodontic care.

Bergersen is clearly devoid of physical teeth markers, such as radiopaque metal spheres or tie points, embedded in a dental appliance as recited by claim 14. Likewise, as explained above in Section I, Jordan et al. also fails to teach or suggest teeth markers, much less markers embedded in a dental appliance. Further, both Bergersen and Jordan et al. fail to teach or suggest "aligning the X-ray information, 3D anatomical information, and the 3D teeth model using the marker information" as required by claim 14.

Secondly, Appellant notes that no motivation or suggestion, either in the cited art references or in the knowledge generally available to one of ordinary skill in the art, has been cited by the Examiner to combine the reference teachings so as to produce the claimed invention. Specifically, there is no suggestion or motivation whatsoever in

any of the references themselves to combine their teachings. Bergersen clearly fails to disclose the use of any teeth markers. Jordan et al. clearly fails to suggest the use of markers embedded in a dental appliance.

Appellant notes that references can not be arbitrarily combined. There must be some reason why one skilled in the art would be motivated to make the proposed combination of references. *In re Nomiya*, 184 U.S.P.Q. 607 (CCPA 1975). Further, the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the cited art references, or how knowledge of those skilled in the art, provide a suggestion or motivation to combine the reference teachings of Jordan et al. with Bergersen so as to produce the claimed invention of claim 14. See *In re Zurko*, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001) ([I]n a determination of patentability .... the Board cannot simply reach conclusions based on its understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings).

As *prima facie* obviousness has not been established, it is respectfully requested that the § 103(a) rejection of independent claim 14 be withdrawn and the claim be allowed.

Independent claim 15 recites similar limitations as those argued above with respect to claim 14. Hence, claim 15 is also in condition for allowance. Claims 16-20 depend from independent claim 15. As argued above, these claims should be allowable for many of the reasons given above with respect to claim 14.

Applicants note that dependent claims 2 and 10 are allowable as they depend from allowable independent claim 1. Claim 10 further requires wearing a dental appliance with one or more marker points. This additional novel and non-obvious limitation is not remotely shown or suggested in the Jordan et al. reference for the reasons argued above with respect to claim 14.

Dependent claim 19 further requires that the markers comprise tie points. This additional novel and non-obvious limitation is not remotely shown or suggested in the Jordan et al. reference for the reasons argued above with respect to claim 11 in Section I.

CONCLUSION

Appellant believes that the above discussion is fully responsive to all grounds of rejections set forth in the Final Office Action dated February 26, 2002.

If for any reasons the Examiner believes a telephone conference would in any way expedite resolution of the issues raised in this Appeal, the Examiner is invited to telephone the undersigned at 415-273-8317.

Respectfully submitted,



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**APPENDIX A**  
**COMPLETE SET OF PENDING CLAIMS**

1                   1.       (Original) A method for integrating anatomical information from a  
2 plurality of sources of information, comprising:  
3                   receiving two or more three dimensional (3D) anatomical maps sharing a  
4 common plane specified by three or more marker points common to the two or more maps;  
5                   placing one or more marker points on one or more teeth;  
6                   generating a digital model of the teeth with the marker points; and  
7                   aligning the two or more 3D anatomical maps and the digital teeth model using  
8 the marker points.

1                   2.       (Original) The method of claim 1, wherein the anatomical information is  
2 stereo craniofacial data.

1                   3.       (Original) The method of claim 1, wherein one of the anatomical map is  
2 an X-ray map.

1                   4.       (Original) The method of claim 3, wherein the X-ray map is generated  
2 using correlated points on X-ray pairs and using y-parallax measurements.

1                   5.       (Original) The method of claim 3, wherein the X-ray information is  
2 stereo.

1                   6.       (Original) The method of claim 3, further comprising calibrating one or  
2 more X-ray sources.

1                   7.       (Original) The method of claim 6, further comprising determining a  
2 principal distance from an X-ray source to a film plane.

1                   8.       (Original) The method of claim 6, further comprising characterizing  
2 internal dimensions of the one or more X-ray sources by locating an X-ray film relative to an X-  
3 ray source.

1                   9.     (Original) The method of claim 1, wherein one of the anatomical map is a  
2 3D image map.

1                   10.   (Original) The method of claim 1, wherein the placing of the markers  
2 further comprises wearing a dental appliance with one or more marker points.

1                   11.   (Original) The method of claim 1, wherein each marker is a tie point.

1                   12.   (Original) The method of claim 1, wherein the aligning uses discrete  
2 anatomical landmark information.

1                   13.   (Original) The method of claim 1, further comprising displaying the  
2 aligned maps as an integrated 3D anatomical model.

1                   14.   (Original) A method for visualizing anatomical information from a  
2 plurality of sources, comprising:

3                   wearing a dental appliance with one or more teeth markers;  
4                   receiving X-ray information having X-ray marker information;  
5                   receiving a three-dimensional anatomical information having anatomical marker  
6 information;  
7                   aligning the X-ray information, 3D anatomical information, and the 3D teeth  
8 model using the marker information; and  
9                   displaying the aligned X-ray information, 3D anatomical information, and the 3D  
10 teeth model.

1                   15.   (Original) A system, comprising:  
2                   an appliance with one or more teeth markers embedded therein;  
3                   an X-ray camera receiving X-ray information with X-ray marker information;  
4                   a three-dimensional digital camera receiving three-dimensional anatomical  
5 information with anatomical marker information;  
6                   a dental scanner to generate a three-dimensional teeth model with teeth marker  
7 information;

8 a computer to align the X-ray information, 3D anatomical information, and the 3D  
9 teeth model using the marker information.

1 16. (Original) The system of claim 15, wherein the X-ray information is  
2 stereo.

1 17. (Original) The system of claim 15, further comprising a calibration array  
2 to calibrate the X-ray camera.

1 18. (Original) The system of claim 15, further comprising an X-ray cassette  
2 carrier.

1 19. (Original) The system of claim 15, wherein each marker is a tie point.

1 20. (Original) The system of claim 15, wherein the appliance comprises a  
2 polymeric shell having cavities and wherein the cavities of the shell have different geometries  
3 shaped to receive teeth.